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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,168

08/18/2006

Karl Mulligan

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8905

23973 7590 01/08/2008

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EXAMINER

DUFFY, BRADLEY

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,168	Applicant(s) MULLIGAN ET AL.	
	Examiner Brad Duffy	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,23-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 18,19,23-29 and 31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20071227</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner of the instant application has changed here at the Patent and Trademark office. Please direct future inquiries concerning this application to Brad Duffy whose telephone number is (571) 272-9935.
2. The response filed November 11, 2007, is acknowledged and has been entered. Claims 1-17, 20-22, 30 and 32-38 have been canceled. Claims 18, 19, 23-29 and 31 have been amended.
3. Upon further consideration, the restriction and election requirement set forth in the Office action mailed May 1, 2007, has been VACATED and a new restriction and election requirement follows.
4. Claims 18, 19, 23-29 and 31 are pending in the application and are currently subject to restriction.

Election/Restrictions

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 18 and 23-27, drawn to a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001, a diagnostic kit comprising said antibody or fragment thereof or a biological targeting

device comprising said antibody or fragment thereof.

Group II, claim 19, drawn to a method of detecting at least one of an astrocytoma cell and a primary breast carcinoma cell in a sample of human cells, which method comprises the step of contacting the cell sample with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001, and detecting those cells which have bound the antibody or fragment, wherein binding of the antibody or the fragment to a cell is indicative of at least one of an astrocytoma cell and a primary breast carcinoma cell.

Group III, claim 29, insofar as the claim is drawn to a method of treating a malignant astrocytoma in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein, which method comprises a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

Group IV, claim 29, insofar as the claim is drawn to a method of treating a malignant melanoma secondary tumour in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein, which method comprises a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

Group V, claim 29, insofar as the claim is drawn to a method of treating a primary breast carcinoma in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein, which method comprises a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

6. Claims 28 and 31 are linking claims, linking the inventions of Groups III-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature recited in claim 18 is a monoclonal antibody or a fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

This claim lacks an inventive step over Immunobiology 5 (Edited by Janeway et al, pages 96-97, 2001). Immunobiology 5 teaches that antibodies comprise numerous fragments including a Fc fragment obtainable by papain cleavage of the antibody (see entire document, e.g., page 96). This Fc fragment is inherently a fragment of the monoclonal antibody obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001. Since Immunobiology 5 teaches the technical feature recited in claim 18, it is not a special technical feature and the groups do not relate to a single

general inventive concept as required under PCT Rule 13.1.

For these reasons, the special technical feature of the invention of Group I is a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

The special technical feature of the invention of Group II is detecting at least one of an astrocytoma cell and a primary breast carcinoma cell in a sample of human cells by the step of contacting the cell sample with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001, and detecting those cells which have bound the antibody or fragment.

The special technical feature of the invention of Group III is treating a malignant astrocytoma in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein by a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

The special technical feature of the invention of Group IV is treating a malignant melanoma secondary tumour in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein by a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

The special technical feature of the invention of Group V is treating a primary breast carcinoma in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein by a step of treating an individual with a monoclonal antibody or fragment thereof obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

8. **Applicant is advised that the reply to this requirement to be complete must**

include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.** The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product

claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding

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is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

bd
January 2, 2008